

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	MDL NO. 1203
)		
)		
THIS DOCUMENT RELATES TO:)	
)		
SHEILA BROWN, et al.)	
)		CIVIL ACTION NO. 99-20593
v.)	
)		
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)		

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8409

Bartle, C.J.

March 5, 2010

Susan Frandsen ("Ms. Frandsen" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Tori Frandsen, Ms. Frandsen's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Thomas S. Davidson, M.D. Based on an echocardiogram dated December 6, 2001, Dr. Davidson attested in Part II of Ms. Frandsen's Green Form that she suffered from moderate mitral regurgitation⁴ and an

3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Davidson also attested that claimant suffered from moderate aortic regurgitation. As Ms. Frandsen's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

abnormal left atrial dimension.⁵ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$534,618.⁶

In the report of claimant's echocardiogram, Charles F. Dahl, M.D., F.A.C.C., F.A.C.P., the reviewing cardiologist, observed that claimant had an enlarged left atrium with a "superior [sic] inferior dimension of 5.5 cm." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

In September, 2002, the Trust advised claimant that her claim was selected for audit.⁷ In response, claimant submitted a

5. Dr. Davidson also attested that Ms. Frandsen had New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for Level II benefits.

7. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit (continued...)

letter from Dr. Davidson and an echocardiogram report prepared by Amjad Iqbal, M.D.⁸ Dr. Davidson stated that claimant's "left atrium measured 5.5 cm in the apical view." Likewise, Dr. Iqbal found that claimant's "[l]eft atrium is mildly enlarged, with ... [antero-posterior] dimensions of 5.5 cm."

In October, 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Davidson's finding that claimant had an abnormal left atrial dimension. Specifically, Dr. Irani measured claimant's left atrial supero-inferior systolic dimension to be 5.2 cm. Dr. Irani also determined that Dr. Davidson improperly measured Ms. Frandsen's atrial dimension "outside [the] left atrial wall [at] 5.49 [cm]."

Based on the auditing cardiologist's diagnosis of a normal left atrial dimension, the Trust issued a post-audit determination denying Ms. Frandsen's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show

7. (...continued)

("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's left atrial dimension. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

8. Although the report prepared by Dr. Iqbal reflects an echocardiogram date of December 5, 2001, the parties do not dispute that this report pertains to the December 6, 2001 echocardiogram claimant submitted with her Green Form.

cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.⁹ The Trust then applied to the court for issuance of an Order to show cause why Ms. Frandsen's claim should be paid. On December 2, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3148 (Dec. 2, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 17, 2004. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor¹⁰ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Sandra

9. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. Frandsen's claim.

10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge—helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had an abnormal left atrial dimension. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Frandsen submitted declarations from Dr. Davidson and Jack Schwade, M.D.¹¹ Each declaration contained the following conclusion:

I have concluded that Ms. Susan Frandsen has an enlarged and abnormal Left Atrium represented by a left atrial supero-inferior systolic dimension in the apical four-chamber view of greater than 5.3 cm, measured by 2-D directed M-Mode or 2-D echocardiography with normal sinus rhythm using sites of

11. Dr. Schwade is no stranger to this litigation. According to the Trust, Dr. Schwade has signed "no fewer than 185 Green Forms" on behalf of claimants seeking Matrix Benefits.

measurement recommended by the American Society of Echocardiography.¹²

Claimant also argues that she has established a reasonable medical basis for her claim based on the detailed findings of her physicians. In addition, claimant contends that "reasonable medical basis" is a fluid term, which incorporates inter-reader variability and allows for variations and disagreements between physicians.¹³ Claimant also submits that: (1) the auditing cardiologist's attestation form, worksheet and certification are incomplete and, thus, do not comply with the Audit Policies and Procedures; (2) the auditing cardiologist's opinion is inadmissible ipse dixit¹⁴ because it fails to explain the lack of a reasonable medical basis; and (3) the Trust's conduct amounts to a violation of her due process rights because she is being deprived of Matrix Benefits without the opportunity to be heard in a meaningful manner. Finally, claimant asserts that because the auditing cardiologist's measurement of her left atrial dimension was a "mere 1 millimeter below the qualifying limit, the Trust has shown only a different diagnosis and not that the

12. Attached to each declaration is one page of three frames from claimant's echocardiogram that purportedly show she has an abnormal left atrial dimension.

13. In support, claimant submitted a partial transcript of testimony from John Dent, M.D., the Trust's expert during the September, 2002 hearings, which ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002).

14. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 847 (8th ed. 2004).

Attesting Physician's opinion is beyond reasonable inter-reader variability or beyond a Reasonable Medical Basis" (emphasis in original).

In response, the Trust forwarded the claim for a second review by Dr. Irani. In a supplemental declaration, Dr. Irani confirmed his previous conclusion that there was no reasonable medical basis for finding that claimant had an abnormal left atrial dimension. Dr. Irani stated that:

Claimant's Attesting and Reviewing Cardiologists rely upon an apical four-chamber view measurement of Claimant's left atrium improperly made in an oblique manner and not parallel to the long axis of the heart. I accurately remeasured Claimant's left atrium on a parallel to the long axis of the heart in the same frame as Claimant's Attesting Cardiologist. I again concluded that Claimant's left atrium is 5.2 cm in the apical four-chamber view.

The Trust also argues that claimant cannot meet her burden of proof simply by proffering opinions from additional physicians. The Trust also asserts that Dr. Irani complied with the Settlement Agreement in the manner in which he reviewed claimant's echocardiogram, and that claimant received adequate notice and an opportunity to be heard with respect to her claim. Further, the Trust contends that claimant's argument concerning inter-reader variability fails to refute the auditing cardiologist's determination that claimant's left atrial

dimension is normal. Finally, the Trust disputes claimant's characterization of the reasonable medical basis standard.¹⁵

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. Specifically, Dr. Abramson stated that:

I measured the left atrium in both acceptable views (as per the Green Form). I measured the left atrial diameter in three different cardiac cycles in the parasternal long axis view at 3.5 cm, 3.4 cm, and 3.4 cm, all of which are within normal limits. The Green Form defines an abnormal left atrium in this view as >4.0 cm. I also measured the left atrial dimension in the supero-inferior axis in the apical-4-chamber view at 5.0 cm, 5.1 cm and 5.0 cm. The Green Form defines an abnormal left atrial dimension in this view as >5.3 cm. These values are all within normal limits. This is a normal-sized left atrium.

The measurement on the tape of 5.49 cm that the technologist made includes the pulmonary vein. I measured a left atrial size of 5.1 cm on that same frame without the pulmonary vein. The tracing that Dr. Davidson and Dr. Schwade incorporated into their exhibits incorrectly includes the mitral valve which resulted in a larger measurement.

In summary, I believe that this left atrium is normal-sized, even allowing for inter-

15. In its reply, the Trust also argues that, under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 at 11 n.13 (Feb. 26, 2007).

reader variability. I believe there is no reasonable medical basis for the Attesting Physician to find this claimant's left atrium to be dilated.

In response to the Technical Advisor Report, claimant argues that: (1) the Technical Advisor's and auditing cardiologist's opinions are ipse dixit expert testimony because there was insufficient reasoning provided for their conclusions; (2) no "legally sufficient analysis" was presented "to dispute the findings of four qualified Cardiologists, especially when the Trust's own Auditing Cardiologist's opinion differed by slightly more than a single millimeter from the Claimant's Cardiologists," (emphasis in original); and (3) the Technical Advisor and auditing cardiologist did not provide any analysis as to why the findings of claimant's cardiologists were outside the bounds of inter-reader variability.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Irani's and Dr. Abramson's conclusions are unsupported. To the contrary, Dr. Irani specifically explained that claimant did not have an abnormal left atrial dimension and that her cardiologists "rel[ied] upon an apical four-chamber view measurement of Claimant's left atrium improperly made in an oblique manner and not parallel to the long axis of the heart."¹⁶

16. We also disagree with claimant that Dr. Irani did not adequately complete the Attestation of Auditing Cardiologist, Auditing Cardiologist Worksheet, and Certification of Auditing Cardiologist.

Likewise, the Technical Advisor Report contains a detailed explanation of how Dr. Abramson reached her conclusions. Dr. Abramson took six separate measurements of claimant's left atrial dimension, all of which were less than the required threshold established by the Settlement Agreement. Moreover, Dr. Abramson determined that the measurement on the echocardiogram tape improperly included the pulmonary vein and that the tracing incorporated into Dr. Davidson's and Dr. Schwade's declarations improperly included the mitral valve. These findings are more than sufficient to support Dr. Irani's and Dr. Abramson's conclusions that there was no reasonable medical basis for the attesting physician's representation that claimant had an abnormal left atrial dimension.¹⁷

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified

17. For this reason as well, we reject claimant's argument that Dr. Irani's and Dr. Abramson's respective conclusions constitute ipse dixit and that Dr. Abramson purportedly substituted her opinion for that of the attesting physician.

Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Irani concluded that Ms. Frandsen's cardiologists "rel[ied] upon an apical four-chamber view measurement of Claimant's left atrium improperly made in an oblique manner and not parallel to the long axis of the heart" and Dr. Abramson determined that the measurement on the echocardiogram tape improperly included the pulmonary vein and that the tracing incorporated into Dr. Davidson's and Dr. Schwade's declarations improperly included the mitral valve. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Further, claimant's argument that inter-reader variability accounts for the discrepancy between the measurements of her physicians and those of Dr. Abramson must fail. As we previously stated, "[t]he concept of inter-reader variability is encompassed in the reasonable medical basis standard." PTO No. 6796 at 7 (Dec. 20, 2006). In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram

demonstrates a normal left atrial dimension. This is especially true where the Technical Advisor specifically accounted for inter-reader variability. Adopting claimant's argument on inter-reader variability would expand the range of abnormal left atrial dimension and would allow a claimant to recover Matrix Benefits when his or her left atrial dimension is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, claimant's argument that the Trust deprived her of due process is without merit. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Policies and Procedures § VI.D. The Audit Policies and Procedures, as approved by this court, comply with due process requirements, as claimant has had notice and an opportunity to present her evidence in support of her claim.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of Ms. Frandsen's claim for Matrix Benefits and the related derivative claim submitted by her spouse.